Elos Accurate® Customized Abutment

Instruction for use

Surgical & Prosthetic Guide

English - Instruction for use (English)
Elos Accurate® Customized Abutment

1. Indications for Use
The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.

The Elos Accurate® Customized Abutments are compatible with the implant systems listed in table 1:

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Nobel Replace NP	3.5	3.5
Nobel Replace RP	4.3	4.3
Nobel Replace WP	5	5
Nobel Replace 6.0	6	6
Nobel CC 3.0	3	3
Nobel CC NP	3.5	3.5 & 3.75
Nobel CC RP	3.9	4.3 & 5
Nobel CC WP	5.1	5.5
Straumann Bone Level NC	3.3	3.3
Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.5/4.0	3.5 & 4	3.5 & 4
Astra Tech 4.5/5.0	4.5 & 5	4.5 & 5
Astra Tech EV 3.6	3.6	3.6
Astra Tech EV 4.2	4.2	3.6 & 4.2
Astra Tech EV 4.8	4.8	4.2 & 4.8
Astra Tech EV 5.4	5.4	5.4
Brånemark NP	3.5	3.3
Brånemark RP	4.1	3.75, 4 & 5
Brånemark WP	5.1	5 & 6

All digitally designed CAD/CAM customizations for the Elos Accurate® Customized Abutments are either intended to be sent and manufactured at a FDA registered Elos Medtech approved milling facility or to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

2. Product Description
The product consists of the Elos Accurate® Customized Abutment and Elos Prosthetic Screw which are manufactured from biocompatible titanium alloy grade 5 ELI ($TiAl_6V_4$ ELI). The Elos Accurate® Customized Abutment is created from the Abutment Blank. The Elos Prosthetic Screw can be layered with a biocompatible low friction coating. The product is available for a variety of implant platforms and sizes. For specific product descriptions, please refer to above table and individual product labels.

The Elos Accurate® Customized Abutment is directly or indirectly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitations and have been designed and manufactured according to CAD/CAM workflow described in section 10. The Customized Abutment is intended for single tooth dental restorations.

A temporary restoration can be used prior to the insertion of the final restoration to maintain, stabilize and form the soft tissue during the healing phase. The temporary restoration may not be placed into occlusion. The Customized Abutment may be placed into occlusion when the implant is fully osseointegrated.

3. Contraindications
- The Elos Accurate® Customized Abutment is not intended for restorations requiring an angle more than 20° or 30° to the axis of the implant. The maximum angulation depend on implant platform compatibility (See table 2).
- Allergies to the alloy or contents of the alloy may very rarely occur.
- The Elos Accurate® Customized Abutment cannot be combined with implants of a different implant type or manufacturer than stated on the label.

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4. Warnings
- The interface of the Elos Accurate® Customized Abutment, which being connected to the implant, must never be changed or modified. Modifications of the interface may result in loss of functionality and/ or infections.
- The product is for single-use only.
- Reuse of the product can result in loss of functionality and/ or infections.
- The Elos Accurate® Customized Abutment must be attached to the implant or abutment using the compatible Prosthetic Screw (refer to table 2).
- Since the Customized Abutment and Prosthetic Screw are small they must be handled with caution to avoid the risk of swallowing or aspiration by the patient.
- Place implant-borne restorations in occlusion only when the implant is completely osseointegrated.
- Always place temporary restorations out of occlusion.
- Allergies to the titanium alloy grade 5 ELI (Ti6Al4V ELI) or contents of the alloy may very rarely occur.
- The Elos Accurate® Customized Abutment components must be used and handled only by dental professionals.
- The use of torque value higher than the recommended may result in damage to the Elos Accurate® Customized Abutment, the Elos Prosthetic Screw and/or the implant. The use of torque values lower than those recommended may result in loosening of the Elos Accurate® Customized Abutment, which may result in damage to the Elos Accurate® Customized Abutment and/or the implant.
- When mounting the Prosthetic Screw, it is important to use a manual screwdriver before using any kind of torque wrench
- Use of any abutment device, scanners, milling units, tools and CAD/CAM software other than those specifically identified as compatible in the labeling, may result in incorrect fit and/or damage of dental restoration.
- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth

5. Precautions
- In order to ensure the best possible conditions for successful working of an implant, it is strongly recommended that the laboratory that designs the superstructure and the surgeon and dentist who install the components all work closely together throughout the processing of the implant.
- Only dental surgeons who have undergone approved training in dental implantology should fit the final abutment. Only laboratory employees with the relevant training should design the final abutment.

6. Potential adverse events
Potential adverse events associated with the use of the Elos Accurate® Customized Abutment products may include: failure to integrate, loss of integration and infection.

7. MRI Safety Information

MRI Safety Information

A person with an Elos Accurate® Customized Abutment, associated dental implant and prosthetic screw may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	Elos Accurate® Customized Abutment
Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil
Operation Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of passive implant devices may produce an image artifact that scales with the device size

8. Cleaning and sterilization

Cleaning:
The Elos Accurate® Customized Abutment and Elos Prosthetic Screw are delivered non-sterile. Prior to installation of the prosthetic restoration in the patient's mouth, it must be sterilized.

FDA-cleared sterilization accessories (i.e., wraps, containers, or indicators) are to be used for the recommended sterilization parameters performed by the end user.

The recommended sterilization procedure is full cycle pre-vacuum steam sterilization at a temperature of 132 °C (270˚F) for 4 minutes. Dry time: 20 minutes.

9. Surgical planning and implant insertion

Elos Medtech is not providing implants. For surgical planning and implant insertion, follow the instruction for use and surgical guide issued by the original implant manufacture.

10. Prosthetic procedure (Approved milling facility)

Using digital workflow (intra-oral scanning):

1. For detection of the precise implant position during scanning, use the Elos Accurate® Scan Body. This must be selected to be compatible with the relevant implant/abutment platform.
2. Scan the patients teeth setup by use of a dental Intra oral scanner

Optional:

3. Create a digital working model in the design software.
4. Export the STL file from the design software and send the STL file to your 3D printer or external 3D print provider.
5. Place an Elos Accurate® Analog for printed models in the 3D printed working model. This must be selected to be compatible with the relevant implant/abutment platform.

Using semi-digital workflow (desktop scanning):

1. Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to representing the implant.
2. Place an Elos Accurate® Scan Body in the analog to identify the position and orientation of this representing the implant.
3. Scan the working model by use of a dental desktop scanner.

Designing and creating the Customized Abutment:
The Elos Accurate® Customized Abutment must be designed using appropriate design software with appropriate library files installed. The material thickness should not be less than 0.4 or 0.5 mm depend on implant platform compatibility (See table 2). The gingival height should not be less than 0.5mm or exceed 5 mm. The maximum angulation should not exceed 30° or 20° depend on implant platform compatibility (See table 2). The post height should not be less than 4 mm.

1. Import the digitized patient information from the intra oral scan to the design software.
2. Import library file and select relevant implant platform from the library
3. Design the Elos Accurate® Customized Abutment in the design software.
4. The digital file of the Elos Accurate® Customized Abutment must be sent to an Elos Medtech approved milling facility for manufacturing.
5. Visually inspect the implant-abutment connection of the customized abutment for any damage which may have been caused during the milling machine processing.

11. Prosthetic procedure (Digital dentistry workflow)

Using digital workflow (intra-oral scanning):

1. For detection of the precise implant position during scanning, use the Elos Accurate® Scan Body. This must be selected to be compatible with the relevant implant/abutment platform.
2. Scan the patient's teeth setup by use of an Intra oral scanner by 3shape. Scanner Accuracy must be 10µm or better (i.e. Intraoral Trios-series).

Optional:

3. Create a digital working model in the design software.
4. Export the STL file from the design software and send the STL file to your 3D printer or external 3D print provider.
5. Place an Elos Accurate® Analog for printed models in the 3D printed working model. This must be selected to be compatible with the relevant implant/abutment platform.

Using semi-digital workflow (desktop scanning):

1. Obtain conventional impression of patient teeth setup and create working model with placed enclosed analog to representing the implant.
2. Place an Elos Accurate® Scan Body in the analog to identify the position and orientation of this representing the implant.
3. Scan the working model by use of a 3shape desktop scanner. Scanner Accuracy must be 10µm or better (i.e. Lab D900, D2000, E-series and D/R2000).

Designing and creating the Customized Abutment:
The Customized Abutment must be designed using 3shape Dental System design software with the relevant Elos Accurate library files installed.

Elos Accurate library file can be downloaded from:
https://elosdental.com/libraries.

Operation manual for 3Shape Dental System can be accessed from:
www.3shape.com

The Elos Accurate library file has built-in design limitations and the user isn't allowed to exceed these limitations. The material thickness should not be less than 0.4 or 0.5 mm depend on implant platform compatibility (See table 2). The gingival height should not be less than 0.5mm or exceed 5 mm. The maximum angulation should not exceed 30° or 20° depend on implant platform compatibility (See table 2). The post height should not be less than 4 mm.

Table 2.

Implant Platform compatibility	Max angulation	Min wall thickness
Nobel Replace NP	30°	0,4 mm
Nobel Replace RP	30°	0,4 mm
Nobel Replace WP	30°	0,4 mm
Nobel Replace 6.0	30°	0,4 mm
Nobel CC 3.0	30°	0,4 mm
Nobel CC NP	30°	0,4 mm
Nobel CC RP	30°	0,4 mm
Nobel CC WP	30°	0,4 mm
Straumann Bone Level NC	30°	0,4 mm
Straumann Bone Level RC	30°	0,4 mm
Astra Tech 3.5/4.0	30°	0,4 mm
Astra Tech 4.5/5.0	30°	0,4 mm
Astra Tech EV 3.6	30°	0,4 mm
Astra Tech EV 4.2	30°	0,4 mm

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Astra Tech EV 4.8	30°	0,4 mm
Astra Tech EV 5.4	30°	0,4 mm
Brånemark NP	20°	0,5 mm
Brånemark RP	20°	0,5 mm
Brånemark WP	20°	0,5 mm

1. Import the digitized patient information from the intra oral scan to the design software.
2. Import library file and select relevant implant platform from the library.
3. Design the Customized Abutment in the design software.
4. Send the digital file of the Customized Abutment to an CORiTEC 350i Pro milling machine by Imes-Icore with MillBox CAM-software using preset settings
5. Mount the Abutment Blank in the holder and manufacture the part with an ø3mm/2mm/1mm radius tooling according to tool manufacturer's instructions.
6. Visually inspect the implant-abutment connection of the customized abutment for any damage which may have been caused during the milling machine processing.

12. Finalizing the prosthetic restoration

1. Place the Elos Accurate® Customized Abutment in the working model with the model analog and a process screw.
2. Complete the crown/bridge restoration following routine laboratory procedures.

13. Use and handling for the dentist

The dentist receives the final dental restoration / working model with the Prosthetic screw from the dental lab.

1. Identify and unpack the Prosthetic screw(s).
2. Clean, disinfect and sterilize dental restoration and Prosthetic screw(s) according to this instruction for use.
3. Remove the healing cap, closure screw or temporary restoration from patient's mouth.
4. Gently, insert the dental restoration into the patient's mouth in proper position to the implant(s) or abutment(s).
5. Place corresponding Prosthetic screw(s) in the dental restoration and tighten screw(s) to the recommended torque (refer to individual screw label or table 2).
6. In order to obtain the recommended torque a dental torque wrench with a suitable screwdriver must be used in accordance with the relevant manufacturer's instructions.
7. The screw channel must always be sealed after the abutment is attached to the implant.

The prosthetic screw compatibility for the Elos Accurate® Customized abutment is listed in table 3.

Table 3.

Implant Platform compatibility	Prosthetic screw	Recommended Screw torque
Nobel Replace NP	AS-NBRM1808POS	35 Ncm
Nobel Replace RP	AS-NBRM2010POS	35 Ncm
Nobel Replace WP		
Nobel Replace 6.0		
Nobel CC 3.0	AS-NBAM1407POS	15 Ncm
Nobel CC NP	AS-NBAM168POS	35 Ncm
Nobel CC RP	AS-NBAM207POS	35 Ncm
Nobel CC WP		
Straumann Bone Level NC	AS-SBOM1608POS	35 Ncm
Straumann Bone Level RC		
Astra Tech 3.0	AS-ATOM148POS	15 Ncm
Astra Tech 3.5/4.0	AS-ATOM168POS	20 Ncm
Astra Tech 4.5/5.0	AS-ATOM2010POS	25 Ncm
Astra Tech EV 3.0	AS-ATEM148POS	25 Ncm
Astra Tech EV 3.6	AS-ATEM168POS	25 Ncm
Astra Tech EV 4.2	AS-ATEM188POS	25 Ncm
Astra Tech EV 4.8	AS-ATEM208POS	25 Ncm
Astra Tech EV 5.4		
Brånemark NP	AS-BRAM167POS	35 Ncm
Brånemark RP	AS-BRAM207POS	35 Ncm
Brånemark WP	AS-BRAM257POS	35 Ncm

14. Instruction for use and maintenance of milling equipment

The original operating manual and maintenance guide for the CORiTEC 350I series by Imes-Icore can be requisitioned by contacting: support@imes-icore.de.

15. Caution

U.S. Federal Law restricts this device to sale by or on order of a dentist or physician.

16. Further information

For additional information about the use of Elos Medtech products, please contact your local sales representative.

17. Validity

Upon publication of this instruction for use, all previous versions are superseded.

18. Storage and Handling

Elos Accurate® Customized Abutment should be stored at room temperature.

19. Disposal

The dental restoration must be disposed as biological waste.

20. Symbols

REF	Catalogue number
LOT	Batch code
	Manufacturer
	Consult instructions for use
	Do not re-use
Rx	Prescription only
	Do not use if package is damaged
NON STERILE	Non sterile
	Recommended torque
	Date of manufacture
MD	Medical device

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UDI	Unique Device Identifier
	Keep dry
	Keep away from sunlight
	MR Conditional

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